K002845

DEC - 8 2000

510(k) Summary

Submitter	Company Name:	**Paragon Vision Sciences**
	Address:	**947 East Impala Ave., Mesa, AZ 85204**
	Phone:	**480-892-7602**
	Fax:	**480-892-3226**
	Registration:	Owner Operator # **9024618**
Material Manufacturer	Company Name:	**Paragon Vision Sciences**
	Address:	**947 East Impala Ave., Mesa, AZ 85204**
	Phone:	**480-892-7602**
	Fax:	**480-892-3226**
	Registration:	**Site Registration #2020433**
Lens Finishing Laboratory	Company Name:	**X-Cel Contacts**
	Address:	**2775 Premier Parkway, Ste. 600 Duluth, GA 30097**
	Phone:	**800-241-9312**
	Fax:	**770-622-8989**
Official Correspondent	Contact:	**William E. Meyers, Ph.D.**
	Company Name:	**Paragon Vision Sciences**
	Address:	**947 East Impala Ave., Mesa, AZ 85204**
	Phone:	**480-507-7606**
	Fax:	**480-892-3226**
Reason for 510(k)	**Change in manufacturing process**	
Date of Submission	**September 11, 2000**	
Device Identification	Trade Names:	**FluoroPerm® 30 (paflufocon C)** **Paragon Thin™ (paflufocon C)** **PVS Basics™ (paflufocon E)**
	Common Name:	**RGP Contact Lens**
	Classification Name:	**Rigid gas permeable contact lens, Class II, for daily wear**
	Reference:	**21 CFR 886.5916, Ophthalmic: 86 HQD**
	Materials Covered By 510k:	**paflufocon C; approved, P870024/S004** **paflufocon E; approved, K984436**

Device Description – Paflufocon C Daily Wear Contact Lenses

FluoroPerm® 30 (paflufocon C) and Paragon Thin™ (paflufocon C) rigid gas permeable contact lenses for daily wear are available as lathe cut firm contact lenses with spherical, aspheric, bifocal or toric anterior, posterior or bitoric surfaces in clear and tinted versions. The posterior curve is selected so as to fit properly an individual eye and the anterior curve is selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

Paflufocon C rigid gas permeable contact lens material is a thermoset copolymer derived primarily from siloxane acrylate, trifluorocthyl methacrylate and methylmethacrylate.

The lens material attributes and lens parameters are found in the Package Insert.

Paflufocon C rigid gas permeable contact lens material is available in untinted (clear) and tinted (blue, gray, and green) versions with or without ultraviolet absorber. The tinted materials contain one or more of the following color additives; D&C Green No. 6, Peroxide Yellow No. 9 and D&C Violet No. 2.

The ultraviolet absorber, Uvinul D-49, has been integrated as an additive within the polymer matrix blocking up to 97% of light below 380 nm. The UV absorber is 2,2'dihydroxy-4,4'-dimethoxy-benzophenone.

No further effort is made here to describe the contact lens itself since it is unaltered in any way from the original product approved under P870024/S004.

Additionally, no effort is made to describe the solution since it is unaltered from the formulation approved in 510(k) Premarket Notification K000148 and its amendments granted to Alcon Laboratories.

Indications For Use

FluoroPerm® 30 and Paragon Thin™ rigid gas permeable contact lenses manufactured from paflufocon C are indicated as a spherical lens for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes who are nearsighted (myopic) or farsighted (hyperopic) and may have corneal astigmatism of 4.00 Diopters or less that does not interfere with visual acuity.

The FluoroPerm® 30 Toric rigid gas permeable contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes who are nearsighted (myopic), farsighted (hyperopic) and to correct astigmatism of up to 6.00 Diopters (D). The FluororPerm® 30 Aspheric rigid gas permeable contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes who are nearsighted (myopic), farsighted (hyperopic) and may exhibit corneal astigmatism up to 4.00 D or less that does not interfere with visual acuity. FluoroPerm® 30 Bifocal rigid gas permeable contact lenses are indicated

for the correction of visual acuity in not-aphakic, presbyopic persons with non-diseased eyes who are presbyopic nearsighted (myopic), farsighted (hyperopic) and may exhibit corneal astigmatism up to 4.00 D or less that does not interfere with visual acuity and up to +4.00 D of add power.

Device Description – Paflufocon E Daily Wear Contact Lenses

PVS Basics™ (paflufocon E) rigid gas permeable contact lenses for daily wear are available as lathe cut firm contact lenses with spherical, aspheric, bifocal or toric anterior, posterior or bitoric surfaces in clear and tinted versions. The posterior curve is selected so as to fit properly an individual eye and the anterior curve is selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

Paflufocon E rigid gas permeable contact lens material is a thermoset copolymer derived primarily from siloxane acrylate, trifluoroethyl methacrylate and methylmethacrylate.

The lens material attributes and lens parameters are found in the Package Insert.

Paflufocon E rigid gas permeable contact lens material is available in untinted (clear) and violet color. The violet tinted material contains D & C Violet # 2 and D & C Red #17.

No further effort is made here to describe the contact lens itself since it is unaltered in any way from the original product approved under K984436.

Additionally, no effort is made to describe the solution since it is unaltered from the formulation approved in 510(k) Premarket Notification K000148 and its amendments granted to Alcon Laboratories.

Indications For Use

The PVS Basics™ (paflufocon E) rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner. The PVS Basics™ (paflufocon E) rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes who are nearsighted (myopic), farsighted (hyperopic) and who may exhibit corneal astigmatism up to 4.00 diopters or less that does not interfere with visual acuity. PVS Basics™ (paflufocon E) toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. PVS Basics™ bifocal lenses are indicated for presbyopic persons (far or near sighted) including astigmatic corrections up to +4.00 D requiring add power of up to +4.00 D.

Packaging

The primary container is identical to that of the predicate device; a glass vial, Type I Borosilicate glass Lawson Mardon Wheaton 4502-B42.

The vial cap is also identical to that of the predicate device. It is comprised of three (3) parts.

- Cap: made of acrylonitrile-butadiene styrene copolymer (Polylac PA-707).
- Extender: made of polypropylene (Profax type PC366).
- Lens Fork: made of polyethylene (NA2707-66).

Please reference P870024/S042 for the material safety data sheets, design and toxicology data.

The Standard Operating Procedures and Forms are identical to those of the predicate device.

Other approved contact lens cases may be used; e.g. Paragon Contact Lens Case (K974635), Paragon Lens Carrier (K993486) and Paragon Lens Vial (K993487). In addition to being approved as lens cases they have been tested under shipping conditions with no evidence of leakage.

The lens is supplied non-sterile in a disinfecting solution. The storage solution acts as a cleaning, conditioning, disinfecting and wetting agent. The solution contains AL 12355™ (hydroxypropyl guar), a unique wetting/conditioning polymer system, polyethylene glycol, tetronic, boric acid, propylene glycol; and, is preserved with PolyQuad® (polyquaternium-1) 0.0011%, and edetate disodium 0.01%.

Bioburden Testing To Evaluate 30-Day Storage In Multipurpose Solution

The lens material used in this testing was paflufocon C. Ten (10) dry packaged lenses, 10 wet packaged lenses selected immediately after packaging and 10 wet packaged lenses which have been set aside and stored under ambient conditions for 30 days post packaging were analyzed for bioburden. It is required that the bioburdens demonstrate that the samples have no more than 100 CFU's per vial. For each sample set a bioburden validation was completed by creating an artificial bioburden (spore inoculation) and determining the percent recovery from the test article. The test articles (10 per sample set) were evaluated for the presence of aerobic microorganisms. The testing was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

Conclusions Drawn from the Bioburden Testing

For each of the three sample sets the result was the same. The test articles, RGP contact lenses, were evaluated for the presence of aerobic microorganisms. Under the experimental conditions employed, the test articles contained No Observed Colonies of

aerobic microbes per lens. The corrected CFU/lens was No Observed Colonies. The test article meets the requirements of the assay (< 100 CFU/lens).

The conclusion is that contact lenses manufactured from Paragon Vision Sciences paflufocon C or paflufocon E materials packaged in a manner identical to the predicate device and shipped in an approved contact lens case containing Alcon RGP Multi-Purpose Disinfecting Solution ID 100136 are safe and efficacious for their intended application.

Equivalence

FluoroPerm® 30 and Paragon Thin™ (paflufocon C), and PVS Basics™ (paflufocon E) when shipped wet are equivalent in their bioburden measured immediately after packaging and after 30 days storage to the predicate product FluoroPerm® 60, Paragon HDS® and Visions™ (paflufocon B). Furthermore, the lenses when shipped wet are equivalent in their material properties to lenses manufactured in the same materials and stored dry.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2000

William E. Meyers, Ph.D.
Vice President, Science and Technology
Paragon Vision Sciences
947 East Impala Ave.
Mesa, AZ 85204

Re: K002845
Fluoroperm^{R}30 (paflufocon C), Paragon Thin^{R}30 (paflufocon C), PVS Basics^{TM} (paflufocon E) Rigid Gas Permeable Lenses for Daily Wear (wet shipping)
Regulatory Class: II
Product Code: 86 HQD
Dated: September 11, 2000
Received: September 12, 2000

Dear Dr. Meyers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications Statement

510(k) Number
(if known):

Device Name: **FluoroPerm® 30 (paflufocon C) and Paragon Thin™ (paflufocon C) Daily Wear Contact Lens**

Indications For Use:

FluoroPerm® 30 and Paragon Thin™ rigid gas permeable contact lenses manufactured from paflufocon C are indicated as a spherical lens for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes who are nearsighted (myopic) or farsighted (hyperopic) and may have corneal astigmatism of 4.00 Diopters or less that does not interfere with visual acuity.

The FluoroPerm® 30 Toric rigid gas permeable contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes who are nearsighted (myopic), farsighted (hyperopic) and to correct astigmatism of up to 6.00 Diopters (D). The FluororPerm® 30 Aspheric rigid gas permeable contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes who are nearsighted (myopic), farsighted (hyperopic) and may exhibit corneal astigmatism up to 4.00 D or less that does not interfere with visual acuity. FluoroPerm® 30 Bifocal rigid gas permeable contact lenses are indicated for the correction of visual acuity in not-aphakic, presbyopic persons with non-diseased eyes who are presbyopic nearsighted (myopic), farsighted (hyperopic) and may exhibit corneal astigmatism up to 4.00 D or less that does not interfere with visual acuity and up to +4.00 D of add power.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

Myra Smith JS

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K00 2845

(Optional Format 1-2-96)

Indications Statement

510(k) Number
(if known):

Device Name: **PVS Basics™ (paflufocon E) Daily Wear Contact Lens**

Indications For Use:

The PVS Basics™ (paflufocon E) rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner. The PVS Basics™ (paflufocon E) rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes who are nearsighted (myopic), farsighted (hyperopic) and who may exhibit corneal astigmatism up to 4.00 diopters or less that does not interfere with visual acuity. PVS Basics™ (paflufocon E) toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. PVS Basics™ bifocal lenses are indicated for presbyopic persons (far or near sighted) including astigmatic corrections up to 14.00 D requiring add power of up to +4.00 D.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Optional Format 1-2-96)

Myra Smith
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002845

JS

TIER II Review: 510(k) Submittal

DATE **September 11, 2000**